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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/665,314

09/19/2003

James J. Cali

02-482-B

6198

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01/15/2009

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EXAMINER

CHUNG, SUSANNAH LEE

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

01/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/665,314	CALI ET AL.	
	Examiner	Art Unit	
	Susannah Chung	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 132-134, 137-139 and 168-220 is/are pending in the application.
- 4a) Of the above claim(s) 191-220 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 132-134, 137-139 and 168-180 is/are rejected.
- 7) ☒ Claim(s) 181-189 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/22/08, 11/12/08, 12/8/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Claims 132-134, 137-139, and 168-220 are pending in the instant application. Claims 1-131, 135-136, and 140-167 are canceled.

Information Disclosure Statement

The information disclosure statement (IDS), filed on 10/22/08, 11/12/08, and 12/8/08 have been considered. Please refer to Applicant's copy of the 1449 submitted herewith.

Response to Non-Final Office Action

Acknowledgment is made of applicant's response and amendment of the claims filed on 10/20/2008.

Claims 132-134, 137-139 and 168 were rejected under 35 U.S.C. 112, first paragraph, because the specification although enabling for a luciferin derivative is not enabled for all compounds "that is a substrate of a cytochrome P450 enzyme and a pro-substrate of a luciferase enzyme" without limitation, i.e. "a compound" reads on all compounds therefore a chemical structure of the compound should be inserted. Applicants arguments have been considered, but are not found persuasive. (See previous office action mail date 7/18/2008, pages 2-5.)

Claims 132, 137, 138, 139, 169, 173, and 177 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the claims contain the trademark or trade name "luciferin," "luciferol," and "dehydroluciferin." Applicants arguments have been considered, but are not found persuasive. (See previous office action mail date 7/18/2008, pages 5-6.)

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Claims 132-134, 137-139, and 168-180 were rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description and enablement requirement because of the scope of the compounds claimed. Applicants arguments have been considered, but are not found persuasive. (See previous office action mail date 7/18/2008, pages 6-7.)

Claims 132-134, 137-139, and 168-180 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention because the substituents are not well defined. Applicants arguments have been considered, but are not found persuasive. (See previous office action mail date 7/18/2008, pages 7-8.)

Claims 132-142 were provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24, 68-71, and 91 of copending U.S. Pat. Appl. No. 11/444,145. This rejection will be addressed towards the end of prosecution because the instant application is senior to the copending application.

Claims 133, 170, 174, and 178 were objected to under 37 CFR 1.75 as being a substantial duplicate of claims from which they depend, i.e. claims 132, 169, 173, and 177 because the composition claim only contained one component. Applicants arguments have been considered, and are found persuasive. (See specification pages 34-35, which support the use of a buffer in the composition.)

Claims 181-189 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Chung whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Golam M. M. Shameem/
Primary Examiner, Art Unit 1626

Susannah Chung, 1/13/2009